PART VIII. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

In response to the requirements addressed by the Safe Medical Devices Act (SMDA) of 1990, a summary follows with the safety and effectiveness information upon which the substantial equivalence determination is based.

K020308

APR 0 3 2002

SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
BIOGEL® SKINSENSE™ POLYISOPRENE SURGICAL GLOVES

1. Submitter Information

SSL Americas, Inc.
3585 Engineering Drive, Suite 200
Norcross, Georgia 30092
Contact Person: Joyce Ning
Telephone No. 770-582-2152

2. Device Name

Classification Name: Non-Latex, Synthetic Surgical Glove
Proprietary Name: Biogel® Skinsense™ Sterile, Powder-Free, Synthetic Polyisoprene Surgical Glove

3. Predicate Device

Primary: Biogel® Neotch II Surgical Gloves (K000421)

4. Description of the Device

The device in this 510(k) submission is intended for the Biogel® Skinsense™ Sterile, Powder-Free, Synthetic Polyisoprene Surgical Glove (Classification number 79KGO). The Biogel® Skinsense™ Sterile, Powder-Free, Synthetic Polyisoprene Surgical Glove is a disposable device made from Non-Latex synthetic rubber material, polyisoprene. Glove size is available from size 5.5 through 9.0 in a half size increment.

5. Indications for Use

The Biogel® Skinsense™ Sterile, Powder-Free, Synthetic Polyisoprene Surgical Glove is a disposable device made of synthetic material and is intended for use in hospitals and other health care facilities during invasive or non-invasive procedures for the protection of operating room personnel and patients, from microbial migration and surgical wounds from contamination.

6. Description of Safety and Substantial Equivalence

The Biogel® Skinsense™ Sterile, Powder-Free, Synthetic Polyisoprene Surgical Gloves are substantially equivalent to the Neotech® II Powder-Free Synthetic Surgical Glove submitted and cleared under 510(k) under K000421. The only major difference is the use of synthetic polyisoprene instead of neoprene polymer with its variations in the formulations. The results of the safety, effectiveness, and performance testing of the this proposed polyisoprene glove are detailed in this 510(k) submission and are summarized as follows:

1. The gloves meet all ASTM D3577-00 requirements for sterility, freedom from holes, physical properties, and physical dimensions.
2. The gloves have been tested and shown to be non-irritating and non-sensitizing under test conditions when evaluated in accordance with internationally recognized test methods.
3. The gloves have been tested per ASTM D6124 and exceed the requirements to demonstrate "powder-free" in nature.

The results enclosed in this submission have demonstrated that the Biogel Skinsense, Powder-Free, Synthetic, Polyisoprene Surgical Glove is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Joyce Ning
Vice President, Regulatory Affairs
SSL America's Incorporated
3585 Engineering Drive, Suite 200
P.O. Box 926090
Norcross, Georgia 30092-9214

APR 0 3 2002

Re: K020308
Trade/Device Name: Regent® Biogel® Skinsense™ Sterile, Powder-Free
Regulation Number: 878.4460
Regulation Name: Surgeon's Gloves
Regulatory Class: I
Product Code: KGO
Dated: January 28, 2002
Received: January 29, 2002

Dear Ms. Ning:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PART V. INDICATIONS FOR USE STATEMENT

3.0

Indications for Use Statement

Applicant: SSL-Americas, Inc.

510(k) Number (if known): K020308

Device Name: Regent® Biogel® Skinsense™ Sterile, Powder-Free Synthetic Polyisoprene Surgeon's Glove

Indications for Use:

The Biogel® Skinsense™ Sterile, Powder-Free, Synthetic Polyisoprene Surgical Glove is a disposable device made of synthetic material and is intended for use in hospitals and other health care facilities during invasive or non-invasive procedures for the protection of operating room personnel and patients, from microbial migration and surgical wounds from contamination.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **or** **Over-The-Counter Use** _____

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
510(k) Number K020308